UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

CHAIRMAN

November 12, 1998

The Honorable Constance A. Morella
United States House of Representatives
Washington, D.C. 20515

Dear Congresswoman Morella:

I am responding to your letter, dated October 13, 1998, that transmitted the concerns of your constituent, Dr. Helena Rodbard, about proposed changes in the U.S. Nuclear Regulatory Commission's (NRC) 10 CFR Part 35 regulations on medical use of byproduct material. In particular, Dr. Rodbard was concerned that the proposed changes in the number of hours of training and experience required for using radioactive materials (I-131) for the treatment of thyroid disease would create an unnecessary burden for physicians, particularly endocrinologists.

The Commission considers the overall issue of training and experience to be one of the most important issues addressed during the rulemaking. Adequately trained personnel are key to the safe use of radioactive material in medicine. The Commission has, therefore, proposed that the training and experience criteria for all users of radioactive material be risk-informed and focused on safety. Throughout the development of the proposed revisions, the staff considered the public input, including comments from the American Association of Clinical Endocrinologists (AACE). The issue of training for endocrinologists that use byproduct material to treat hyperthyroidism and thyroid cancer was discussed in a Commission public meeting in June 1998. At that time, the Commission directed the staff to study the issue further and provide a basis for its proposed position.

On August 13, 1998, the proposed rulemaking was published in the Federal Register, for a 90-day public comment period. A series of public meetings was also scheduled during the comment period. These meetings took place August 19-20, 1998, in San Francisco, California; September 16-17, 1998, in Kansas City, Missouri; and October 21-22, 1998, in Rockville, Maryland. Details of the scheduling of the public meetings were published in the Federal Register on July 24, 1998 (63 FR 39763). As noted in the Federal Register notice for these meetings, the Commission, through the facilitator for the meetings, invited participants that represent a broad spectrum of interests which may be affected by the proposed rulemaking. The AACE staff worked with the NRC staff to ensure that the endocrinologists' interests were represented at these meetings.

The Commission plans to carefully evaluate all the public comments in finalizing the training and experience requirements for users of byproduct material.

Sincerely,

Shirley Ann Jackson